

United States District Court

MIDDLE

DISTRICT OF

ALABAMA

In the matter of the Search of
(Name, address or brief description of person, property or
premises to be searched)

Nutrition2000

4108 Rucker Blvd.

Enterprise, AL 36330

APPLICATION AND AFFIDAVIT FOR SEARCH WARRANT

CASE NUMBER: 1:07mj 15-SRW

I Robert Kuykendall being duly sworn depose and say:

I am a(n) Special Agent, U.S. Food and Drug Administration, Office of Criminal Investigations and have
reason to believe that ☐ on the person of or ☒ on the property or premises known as (name, description and/or location)

See Attachment A

in the Middle District of Alabama

there is now concealed a certain person or property, namely (describe the person or property to be seized)

See Attachment B

which is (state one or more bases for search set forth under Rule 41(b) of the Federal Rules of Criminal Procedure)

**Evidence of a crime, contraband, fruits of crime, and other items illegally possessed, and property designed
for use, intended for use, or used in committing a crime,**

concerning a violations of Title 18, U.S.C. §1341 and 21 U.S.C. §331 and §333.

RETURNED AND FILED

The facts to support the issuance of a Search Warrant are as follows:

FEB 12 2007

See Affidavit

Continued on the attached sheet and made a part hereof: ☒ Yes ☐ No

CLERK
U. S. DISTRICT COURT
MIDDLE DIST. OF ALA.

Robert O. Kuykendall
Signature of Affiant

Sworn to before me and subscribed in my presence,

February 6, 2007 at
Date

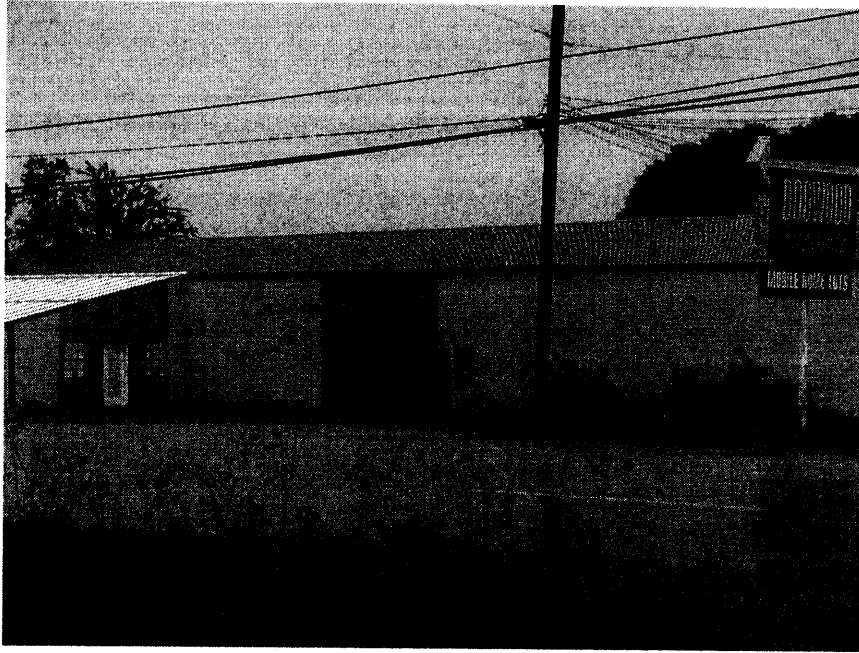
Montgomery, Alabama
City and State

Susan Russ Walker, U.S. Magistrate Judge
Name & Title of Judicial Officer

[Signature]
Signature of Judicial Officer

Attachment A – Description of Address to be Searched

4108 Rucker Blvd, Enterprise, AL 36330 is a metal warehouse/building tan in color with a red roof. The building is located approximately 40 feet from Rucker Blvd. A door facing Rucker blvd has the number 08 attached.



Attachment B – Items To Be Seized

The following items are to be seized, whether hard copies or electronically stored:

Personal and business records related to the manufacture, advertising, labeling, purchase, sale, and/or transfer of PC Hope, Calcium D'Glucarate or Prostalife. These records include, but are not limited to labels and label machines, books, records, receipts, notes, ledgers, letters of credit, correspondence, memorandums, mailing envelopes, facsimiles, purchase orders, purchase invoices, purchase agreements/contracts, sales invoices, licenses, applications, and shipping records.

Financial records of Nutrition2000 and/or company managers including but not limited to account statements, credit card statements, third party invoices, and tax records.

PC Hope, Calcium D'Glucarate, Prostalife, or any components thereof.

Equipment used in the manufacture of PC Hope, Calcium D'Glucarate or Prostalife.

Affidavit

I, Robert D. Kuykendall, depose and state as follows:

1. I am a Special Agent with the United States Food and Drug Administration, Office of Criminal Investigations (FDA/OCI). I have been a federal law enforcement agent for 12 years and have been the Affiant in numerous Applications for Search Warrant related to narcotics, child exploitation, complex fraud investigations, and violations of the Food Drug and Cosmetic Act. Additionally, I have participated in the execution of at least 80 Search Warrants. I have received federal law enforcement training at the Federal Law Enforcement Training Center (FLETC), and the United States Postal Inspection Service's training academy in Potomac, Maryland.

2. I have been engaged in an investigation involving Nutrition2000, 4108 Rucker Blvd., Enterprise, Alabama, operated by Larry Pope, and possibly Mr. Pope's wife and daughter Debra Pope and Alice Pope respectively. This case involves the manufacture, advertising, and distribution of unapproved and misbranded drugs including PC Hope, Calcium D'Glucarate, Prostalife, and other cancer-drugs reportedly manufactured by Nutrition2000, and for fraudulent and misleading representations made in connection with the sale of this and other drugs. The facts contained in this Affidavit have been obtained through my investigation and information provided by other law enforcement agents.

Applicable Criminal Statutes

3. The U.S. Food and Drug Administration (FDA) is an agency of the United States Government charged with the responsibility of protecting the American public by enforcing the FD&C Act, 21 U.S.C. §§301-395, to ensure that the drugs sold for administration to humans are safe, effective and bear labeling containing true and accurate information.

4. 21 U.S.C. §321(g) defines *drug*, in relevant part, as (1) any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal; (2) any article (other than food) intended to affect the structure or any function of the body; or (3) any article used as a component of either.

5. The FD&C Act defines *new drug* as any drug the composition of which is not generally recognized by experts as safe and effective for the use under the conditions prescribed, recommended or suggested in the labeling. 21 U.S.C. §321(p)

6. The FD&C Act provides that before a new drug can be shipped in interstate commerce, its manufacturer first has to obtain FDA approval of a New Drug Application (NDA) for that drug. 21 U.S.C. §§355(a) and 331(d). The manufacturer of a new drug is required to submit information in the NDA showing to the FDA's satisfaction that its new drug is safe and effective for its intended use. 21 U.S.C. §355(b)(1); 21 C.F.R. §314.50

7. The FD&C Act states that a drug shall be deemed misbranded if its labeling is false or misleading in any particular. 21 U.S.C. §352(a) Labeling is defined as "all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article." 21 U.S.C. §321(m)

8. Under the FD&C Act, a drug is deemed misbranded unless its labeling bears (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner or form as are necessary for the protection of users. 21 U.S.C. §352(f) FDA by regulation, 21 C.F.R. §201.5, defines "adequate directions for use" to mean "directions under which the layman can use a drug safely and for the purposes for which it is intended."

9. 21 U.S.C. §331 prohibits the following acts and the causing thereof:

- a. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded. 21 U.S.C. §331(a);
- b. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a drug if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being misbranded. 21 U.S.C. §331(k); and
- c. The introduction or delivery for introduction into interstate commerce any new drug unless an application for that drug has been filed with the FDA. 21 U.S.C. §§331(d), 355.

10. The FD&C Act establishes criminal penalties for doing or causing any of the above mentioned prohibited acts. Under 21 U.S.C. §333(a)(1), any person who violates a provision of 21 U.S.C. §331 shall be imprisoned for not more than one year or fined not more than \$1,000 (i.e. a misdemeanor). Notably, this is true even if an act is committed without specific intent. United States v. Park, 421 U.S. 658 (1975). Pursuant to 21 U.S.C. §333(a)(2), if a person commits a second violation of 21 U.S.C. §331 after final conviction on the first charge, or commits such violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000 or both (i.e. a felony).

11. 18 U.S.C. §1341 proscribes the use of the mails or any private or commercial interstate carrier in furtherance of a scheme to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations or promises.

Investigative Facts

12. On March 15, 2006, SA Kuykendall telephonically contacted Dr. Robert Baratz, President of the National Council Against Health Fraud, regarding an Email he sent to FDA/OCI alerting agents to an Enterprise, Alabama company (Nutrition 2000) advertising products for sale for the cure of prostate cancer. Dr. Baratz had been made aware of the company by a Lind, MN patient who sought treatment from Nutrition 2000 before beginning traditional cancer treatment. In the February 27, 2006 Email, Baratz's patient, Mrs. Bridie Klein wrote, "[My husband] delayed surgery until he went on this 40 day miracle cure that by phone they told him he would be cured guaranteed and to not have the planned surgery. Well, after the 40 days not only did it not work at all, but he became toxic on the selenium (sic) part of this very extensive group of herbal concoctions taken 11 different times of the day as well being so disappointed."

13. On March 15, 2006, Affiant reviewed the Website nutrition2000.com and found many claims about this company's cancer treatment. The following paragraphs (A - D) include a few of the numerous claims.

- A. "Studies show that delaying any conventional treatment such as surgery or radiation will not affect the eventual outcome of those treatments. Therefore, even if our program fails to help you, you will not be penalized. Most of our clients who do opt to proceed with conventional treatments, while they are few, do relate to us how amazed their doctors are at how well they do."
- B. "Perhaps you are being pressured into becoming a sitting duck for the normal Establishment treatments, namely chemo, radiation and surgery (the Big 3). Last year, billions were spent on these cures, which often leave you worse off than before you started treatment...Fortunately, there's no need for you to suffer those indignities. With our new program, it is now possible to control your cancer naturally, without the harmful side effects associated with the Big 3." These comments were made regarding Nutrition2000's "Cancer Protocol."
- C. Regarding PC Hope, the following claim is made on the Nutrition2000's Website. "PC Hope is specifically formulated with all-natural ingredients that have been successfully used by men around the world for relief of prostatitis, BPH, elevated PSAs and all stages of Prostate Cancer, without many of the side effects associated with conventional medications and treatments."
- D. Regarding Men's Prostalife, the following is a description of the product listed on the Nutrition2000 Website. "A natural progesterone cream made exclusively for men. Benefits include:

Decrease in prostate enlargement. Decrease in urinary urgency. Increase in libido and sexual performance. Slows or stops the growth of prostate cancer.”

14. Affiant requested a review of the Nutrition2000 Website by the FDA’s Center for Drug Evaluation and Research (CDER) for comment and opinion of the company’s drug claims. Linda Silver, DVM, MPH, Team Leader of the Internet and Health Fraud Team, Office of Compliance, advised Affiant that the claims made were in fact drug claims and rendered PC Hope a drug under FDA regulations. Silver further commented that, “The products are clearly violative, with serious disease claims (claims to treat prostate cancer), representing serious indirect health hazards at minimum. It is particularly alarming that the Website discourages patients from getting traditional therapies that could actually benefit them!”

15. Pursuant to the request for review, on February 5, 2007, Vesna Stanoyevitch, Office of Compliance, FDA Center for Drug Evaluation and Research, subsequent to a review of labeling and advertising of Nutrition2000’s Prostalife, advised, “Claims such as, “slows or stops the growth of prostate cancer,” and “decrease in prostate enlargement,” are drug claims. Topical progesterone creams that are labeled with drug claims cause the product to be a drug and a new drug in violation of the Final Rule, 21 CFR 310.530(b). This rule states that any OTC drug product, other than hydrocortisone, that is labeled, represented, or promoted as a topically applied hormone-containing product for drug use is regarded as a new drug for which an approved application is required for marketing.”

16. On May 2, 2006, an undercover purchase of one bottle of PC Hope (90 capsules) was made via the Internet, from Website www.nutrition2000.com.

17. On May 4, 2006, the above ordered product was received from the “shipping department,” Nutrition2000, 4108 Rucker Blvd, Enterprise, AL 36330. The package was sent via United States Postal Service. Neither the bottle nor the labeling provided instructions for use to treat cancer.

18. On May 16, 2006, Affiant telephonically contacted Nutrition2000 and spoke with Mr. Larry Pope, identified on the Website as company owner. Affiant advised Pope he (Affiant) worked with an alternative medical clinic in Georgia and wanted to discuss the purchase of a significant quantity of cancer treatment products from Nutrition2000. Pope discussed Nutrition2000 and stated he had the highest success rate in the world with cancer. Pope said he had 30,000 clients world-wide, and 48% are international. He stated he has been in business for twelve years and has the highest users of alternative products in the country. Pope stated he has a medical doctor in Mexico overseeing the production of one new product, and one of his best “formulators” is in Israel. Pope stated, “If I can’t stop cancer in the human body, no one on the face of the Earth can.” Pope claimed to be an expert in prostate and breast cancer. He said the government had “put a lot of pressure on me and actually made me stop for year and half,” so he moved some of his operation to Mexico. Pope stated Affiant needed to focus

on breast and prostate cancer because he (Pope) has a product that is very expensive, and doesn't offer a lot of profit on its own, but is a "great draw" and can be added with other profitable products. Pope was asked if you have to be licensed in each state where you ship and he said it was "a bunch of bull" because he ships products all over the world. Affiant explained he wanted to meet Pope to discuss being a "middle-man" for the distribution of Nutrition2000 cancer-related products and wanted to ensure the products were patented or trade-marked by Nutrition2000 and not a third party. Pope advised all his products were private labeled and he spends over \$30,000 on a lot of companies each month and, "they're not gonna open their mouths because it's coming from me. You know what I'm saying?" Affiant asked Pope if a meeting could take place at his Enterprise, Alabama office, and Pope advised he allowed no one inside his facilities, but could meet for lunch in the South Alabama area. Pope advised he looked forward to future orders by Affiant.

19. On June 2, 2006, Mike Hiser, FDA/OCI Atlanta Resident Agent in Charge, conducted surveillance at 4108 Rucker Blvd., Enterprise, Alabama 36330. The address appeared to be in a row of warehouses made of metal construction. There was a large sign in the front area which apparently identified several of the businesses that rent the facilities. The sign reads, "Wilkins Industrial Park #3." There was no sign attached to the first metal warehouse indicating what type of business is there. There were several windows and the blinds/shades were all closed tightly. On the front of the bldg the numbers "08" were displayed with new siding located where the numbers "48" should be located. There were no vehicles parked in the front of the building next to the street. The following Alabama license plates were taken from vehicles parked behind the building: 26C399L; 26D490M; 19B573Z; 19C904W; 19C654V; and 19C455Y.

20. On June 16, 2006, RAIC Hiser requested automated searches of the above license plates and found the following: 26C399L: Scott, Bridget, 283 Phyllis Ave., Enterprise, AL 36330; 26D490M: Small, Patrisha, 3940 Rucker Blvd Lt 1, Enterprise, AL 36330; 19B573Z: Pope, Amanda, 705 North Main Street, Enterprise, AL 36330; 19C904W: Miranda, Karen, PO Box 94, New Brockton, AL 36351; 19C654V: Dubose, Jackie, 203 Wellston Drive, Enterprise, AL 36330; 19C455Y: Duiven, Ehwa or Jesse, 41 Cotton Creek Blvd, Enterprise, AL 36330.

21. On June 19, 2006, RAIC Hiser conducted surveillance at 4108 Rucker Blvd., Enterprise, AL 36330. There were no vehicles parked in the front of the building next to the street. The following Alabama license plates were recorded from the vehicles parked behind the building: 26C399L; 19C904W; 19C654V; 19C455Y and 19C974L. All previously identified but the later, which was found to be registered to Pope, Amanda, 825 N. Main St. Enterprise, AL 36330.

22. On June 23, 2006, RAIC Hiser conducted a trash pull at 4108 Rucker Blvd., Enterprise, AL 36330. The items found within the trash, recorded on a FDA/OCI Certified Inventory of Evidence (CIE) Form, included:

- a. Numerous invoice receipts to customers across the United States. The receipts include individuals and business entities.
- b. Labels reflecting other products being sold under the Nutrition2000 name including DMSO, Menopause Plus, Rephe Flora, Surcan, Cesium/Potassium, Hormone Balance.
- c. Tax records for Alice Pope (422-31-2111) reflecting an income of \$165,000 and listing dependents as Larry D. Pope Senior (422-70-4656) and Deborah Pope (422-70-2056).
- d. Email correspondence to customers from (as indicated by the Email) Larry Pope. One customer discussed a payment of \$695 for treatment of stomach cancer. In a separate Email, Pope states, "Do not listen to the hospial (sic) – it is the same old dog and pony show – keep me posted – thanks."

23. On November 14, 2006, Affiant telephonically contacted Nutrition2000 at the toll-free number listed on the company Website (800-558-9697). An automated recording (female voice) welcomed Affiant to Nutrition2000 and directed Affiant to press 290 for new orders; 223 for new orders or customers wishing to speak with Larry; 224 for existing customers wishing to speak with Jim; or 222 for existing customers wishing to speak with Chris. Affiant pressed 290 and the phone was answered by a male identifying himself as Chris. Affiant identified himself as Robert Kay and told Chris about the previous order of PC Hope. Chris advised he "saw" the order was placed previously for \$89.95. Affiant told Chris plans were underway to open a new company, "Professional and Licensed Partners," and the previous order was made to experiment with the product before offering it to patients. Affiant said the company startup was interrupted by a death in the family, but was now underway. Chris told Affiant the company was still offering the PC Hope product, but had now started selling a new product, Calcium D'Glucarate, which was to be taken with the PC Hope capsules. Chris stated they recently had a "patient" reduce his PSA levels 15 points in 11 days by taking the two capsules daily. Chris advised the price of the new product was \$49.95 for 120 capsules, but Larry would most likely sell it to Affiant's company at wholesale. Chris offered that the wholesale price on the PC Hope is \$69.00. Chris stated he was the company's Web designer, but was now a trained consultant. He provided his last name as Miranda.

24. On February 2, 2007, Affiant conducted a review of the FDA's Center for Drug Evaluation and Research database for approved drug products and found no approved New Drug Application (NDA) for PC Hope, Prostalife or Calcium D'Glucarate. Affiant also searched CDER's "Orange Book" for drug approvals submitted by Larry Pope, Nutrition2000, and the above product names and found no approvals or listings.

25. On January 18, 2007, RAIC Hiser and SA Kuykendall conducted surveillance/investigation at 4108 Rucker Blvd, Enterprise, Alabama 36330. Three vehicles were located behind the warehouse including a black BMW 323i bearing Alabama license plate 19C458H. This vehicle was later found to be registered to Amanda Pope, 4108 Rucker Blvd., Enterprise, Alabama 36330.

26. On January 18, 2007, at approximately 11:15AM, SA Kuykendall knocked on the front door (white door) of the warehouse nearest Rucker Blvd. The front of the warehouse has two doors, one red and one white. The red door was observed to have weeds and dirt in front of it, appearing as though it was rarely used. The white door was opened by an unknown white male. SA Kuykendall inquired about the warehouse units and the unknown male advised that the first building, and only the first building, (nearest Rucker Blvd) was owned by Larry Pope. The man stated that he was unsure who owned the other three warehouses, but stated Pope would be able to provide a telephone number for the owner or renter. The unknown male advised SA Kuykendall could call Pope at 334-347-6800.

27. On February 6, 2007, Affiant telephonically contacted Nutrition2000 (334-558-9697) and spoke with an individual identifying himself as Chris. This sounded like the same individual who previously identified himself as Chris Miranda. Affiant told Chris he (Affiant) was attempting to determine the exact cost for ordering two bottles of PC Hope and two bottles of Calcium D'Glucarate including shipping to Atlanta. Affiant explained this information was needed for an "associate" who was requesting company funds for the purchase and needed the exact amount. Affiant also asked why the product could not be found on the Website to which Chris responded, "We don't post "CDG" on the Web because it's pharmaceutical grade." Chris advised the total price would be \$251.40.

28. On February 6, 2007, subsequent to a review of the claims and comments made by a representative of Nutrition2000 regarding the company's Calcium D'Glucarate, Mrs. Kristen Moe, FDA's Center for Food Safety and Applied Nutrition relayed that claims made about the product (related to the 15 point reduction of PSA levels in 11 days experienced by one Nutrition2000 "patient" by taking the Calcium D'Glucarate and PC Hope together), coupled with the fact that Nutrition2000 is encouraging the use of Calcium D'Glucarate with PC Hope (further showing intended use), would make the statements drug claims and would subject the drug to the requirement of an approved application before marketing.

29. Based upon the facts stated herein, as well as Affiant's investigative experience, I know that businesses routinely maintain records and related correspondence pertaining to their business at locations where such business is conducted. These records are routinely in the form of business ledgers, sales invoices, sales receipts, customer lists, supplier lists, financial ledgers, shipping information, and correspondence files. It is also the experience of this affiant that such records are maintained in both hard copy and in computer generated files. Accordingly, Affiant submits that there is probable cause to believe that correspondence, computer records and other business records (as more fully

described in Attachment B) that contain information relevant to the crimes set forth herein are presently located within the business/residence located at 4108 Rucker Blvd, Enterprise, Alabama 36330. And further, that such evidence constitutes fruits, evidence and/or instrumentalities of criminal offenses against the United States.

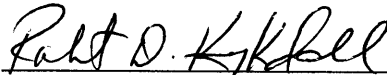
Computer Evidence

30. Based upon my training, experience and knowledge obtained from the Seized Computer Evidence Recovery Specialists assigned to OCI, I know that in order to completely and accurately retrieve data maintained in computer hardware or on computer software, to insure the accuracy and completeness of such data, and to prevent the loss of the data either from accidental or programmed destruction, it is often necessary that some computer equipment, peripherals, related instructions in the form of manuals and notes, as well as the software utilized to operate such a computer, be seized and subsequently processed by a qualified computer specialist in a controlled environment.


31. Based on my knowledge, training, and experience, and the experience of other law enforcement personnel with whom I have spoken, I am aware that searches and seizures of evidence from computers taken from the subject premises commonly require agents to seize most or all of a computer system's input/output peripheral devices, in order for a qualified computer evidence recovery specialist to accurately retrieve the system's data in a controlled environment. Therefore, in those instances where computers are removed from the subject premises, and in order to fully retrieve data from a computer, investigators must seize all magnetic storage devices, as well as the central processing units (CPUs) and applicable keyboards and monitors which are an integral part of the processing unit. If, after inspecting the input/output devices, system software, and pertinent computer-related documentation, it becomes apparent that these items are no longer necessary to retrieve and preserve the data evidence, such materials and/or equipment will be returned within a reasonable time.

32. The analysis of electronically stored data, whether performed on-site or in a controlled environment, may entail any or all of several different techniques. Such techniques may include, but shall not be limited to, surveying various file "directories" and the individual files they contain (analogous to looking at the outside of a file cabinet for the marking it contains and opening a drawer capable of containing pertinent files, in order to locate the evidence and instrumentalities authorized for seizure by the warrant); "opening" or reading the first few "pages" or such files in order to determine their precise contents; "scanning" storage areas for deliberately hidden files; or performing electronic "key-word" searches through all electronic storage areas to determine whether occurrences of language contained in such storage areas exist that are intimately related to the subject matter of the investigation.

33. Wherefore, your Affiant respectfully requests a Search Warrants authorizing the search of the business located at 4108 Rucker Blvd, Enterprise, Alabama 36330, and the seizure of any and all documents, unapproved drugs or components thereof, correspondence, medical and clinical information, financial records and computer data, including hard drives, discs and any other magnetic or electronic media, related or referring to the promotion or sell of unapproved and/or misbranded drugs.


Robert D. Kuykendall
Special Agent, FDA

Sworn and subscribed before me this 6th day of February, 2007


United States Magistrate Judge